

REMARKS

Claims 128 and 130-143 are pending in this application. Claim 133 is objected to under 37 C.F.R. § 1.75(c) for being presented in improper dependent form. Claim 132 is rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. Claims 128 and 136-141 are rejected under 35 U.S.C. § 102(b) for anticipation by Constantz et al. (U.S. Patent No. 5,336,264; hereinafter "Constantz") and claims 128 and 130-143 are rejected under 35 U.S.C. § 102(e) for anticipation by Lee et al. (U.S. Patent No. 6,132,463; hereinafter "Lee"). By this reply, Applicants cancel claims 133-1345, amend claims 128, 130, 132, 135, and 140, add new claims 144-148, and address each of the Examiner's rejections below.

Support for the Amendment

Claim 128 is amended to correct syntax and has been amended to recite the limitations of cancelled claim 133. Support for the amendment to claim 132 is found in the specification at page 70, lines 8-15. Claim 135 has been amended to eliminate redundancies in the claim and to include additional biologically active agents described in the specification. Support for the amendment to claim 135 is found in the specification at, e.g., page 43, lines 6-9, page 44, lines 6-17, page 49, lines 8-13, page 51, lines 17-21, page 62, line 12, through page 64, line 17, and page 71, lines 6-10. Claim 140 is amended to correct the typographical omission of "phosphate". Support for new claims 144-148 is found in the specification on, e.g., page 15, line 21, through page 16, line 20. No new matter is added by the amendment.

Objection under 37 C.F.R. § 1.75(c)

Claim 133 was objected to for being in improper dependent form. Claim 133 has been cancelled. Therefore, the objection to claim 133 can be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 132 is rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. The Examiner states that there is insufficient antecedent basis in claim 128 for the limitation “the at least one bone-resorbing cell”, and that “in the opinion of the examiner...claim 132 should have depended from claim 131, not from claim 128” (Office Action, p. 3). Claim 132 has been amended to correct the improper claim dependency. It now correctly depends from claim 131. The rejection of claim 132 can now be withdrawn.

Rejections under 35 U.S.C. § 102

Constantz

The Examiner rejects claims 128 and 136-141 under 35 U.S.C. § 102(b) for anticipation by Constantz, stating that Constantz discloses a composition comprising calcium phosphate in which a variety of additives, such as bone associated proteins, “may be added to modify the physical properties of the composition, enhance resorption, bone formation, growth of osteoclasts and/or osteoblasts, etc.” (Office Action, pp. 3-4). Applicants have amended claim 128 to recite an implant containing three components: a calcium phosphate, an agent which directly or indirectly stimulates osteoclast activity, and a biologically active agent. The agent which directly or indirectly stimulates osteoclast activity is provided to aid in the resorption rate of the implant,

while the biologically active agent is included in the composition to aid in the diagnosis of disease, to cure, mitigate, treat, or prevent a disease, or to enhance the physical or mental development or condition of the recipient of the implant (see, e.g., page 35, lines 4-10, and page 56, lines 18-21).

Constantz merely describes a hydroxyapatite bone cement that may optionally contain an additive, e.g., a protein, which modifies the physical properties of the bone cement. Constantz fails to teach or suggest that the bone cement contains both an agent which directly or indirectly stimulates osteoclast activity and a second biologically active agent.

The M.P.E.P. § 2131 states that “‘A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” It is also established that when the claimed combination is not specifically named in the prior art, but instead, it is necessary to select portions of the teachings within a reference and combine them, anticipation can only be found if the classes or substituents are sufficiently limited or well delineated. See M.P.E.P. § 2131.02, citing *Ex parte A* 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). The Federal Circuit in *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.* stated that “although specific claims are subsumed in a [prior art reference’s] general disclosure...this is not literal identity.” 24 USPQ2d 1321 (1992). Thus, when a reference does not provide guidance on how to construct a product with the claimed beneficial properties, it is not anticipatory.

Constantz fails to teach or suggest that the composition contains both an agent which directly or indirectly stimulates osteoclast activity and a biologically active agent. Constantz

merely lists additives that may optionally be included in the hydroxyapatite bone cement, but fails to disclose a bone cement that is prepared with both an agent which directly or indirectly stimulates osteoclast activity and a biologically active agent. Because Constantz fails to teach or suggest an implant containing all of the components recited in present claim 128 (i.e., a calcium phosphate, an agent which directly or indirectly stimulates osteoclast activity, and a biologically active agent), Constantz fails to anticipate claim 128, and claims dependent therefrom (see M.P.E.P. § 2131, *supra*). Therefore, Applicants respectfully request that the rejection of claims 128 and 136-141 under 35 U.S.C. § 102(b) for anticipation by Constantz be withdrawn.

Lee

Claims 128 and 130-143 are rejected under 35 U.S.C. § 102(e) for anticipation by Lee. Applicants note that the instant application claims priority to Lee, as is evidenced by the domestic priority data listed on the filing receipt (provided herewith). Therefore, Applicants respectfully submit that the rejection of claims 128 and 130-143 under 35 U.S.C. § 102(e) for anticipation by Lee is improper and should be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including March 16, 2004, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any other charges or any credits, please apply them to Deposit Account No.

03-2095.

Respectfully submitted,

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Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045